

PATENT

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Attorney Docket No. A-68717-2/RMS/VEJ  
Application No. 09/881,052***Claim Objections***

The Examiner made various objections to the Claims. Applicants respectfully submit that the accompanying amendment to the claims renders such objections moot.

***Rejections under 35 U.S.C. § 112***

The Examiner has rejected claims 40-43, 47-49, 54, 67, 68, 71-75, 82, 86 and 87 under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. As noted above, claims 77-88 have been cancelled thus rendering the Examiner's rejection of claims 82, 86 and 87 moot.

Applicants respectfully traverse the Examiner's rejection of claims 40, 41, 67 and 68. The operation of a rotary actuator (e.g., circular arm 69 of positioning mechanism 67) is described in detail in the specification. For example, the operation of the rotary actuator is discussed on at least page 14, line 11, through page 16, line 19, and illustrated in FIG. 4.

Applicants respectfully traverse the Examiner's rejection of claims 42, 43, 71 and 72. The actuation of the nozzles and dispensing fluid while the rotor or dispensing head is moving along the circular path is described in detail in the specification as originally filed. For example, relevant discussion may be found on page 2, lines 28-32, page 3, lines 13-15, page 11, lines 26 *et seq.* ("reagent delivery dispenser 52 of the present invention is capable of addressing each well 41 individually while microtiter plate 42 is moving *while rotor assembly 46 is spinning*", *emphasis added*), page 13, lines 31 *et seq.* ("with out stopping dispenser head"), page 16, lines 4 *et seq.* ("because a continuous path system is established, the reagent dispenser head 60 may traverse over microtiter plate 42, *with both components in constant motion*" *emphasis added*), and a number of other occasions. The Examiner notes that the drawings are not sufficient to illustrate the functional limitations of these claims. Nonetheless, Applicants respectfully submit that FIG. 3 schematically illustrates nozzles of the reagent delivery head (e.g., dispenser head) *while the wells are in motion*, as indicated by arrow A.

## BEST AVAILABLE COPY

PATENT

Attorney Docket No. A-68717-2/RMS/VEJ  
Application No. 09/881,052

Applicants respectfully traverse the Examiner's rejection of claims 47-49 and 73-75. The application, as originally filed, sets forth that the reagent dispenser 52 is a multi-channel dispenser that is capable of simultaneously delivering a plurality of different liquids to corresponding different sets of wells. *See* page 10, lines 18-19. One would appreciate that a multi-channel dispenser is one which has multiple sets of nozzles, each capable of delivering a respective liquid to a respective set of wells. Further, the application also describes that the multi-channel dispenser 52 is capable of sequentially delivering a plurality of different liquids to the wells. *See* page 10, lines 20-21. Furthermore, FIG. 3 schematically shows an exemplary two-channel delivery configuration having a first nozzle 65' filling one set of wells with a first reagent, and a second nozzle 65'' filing another set of wells with a second reagent. One would understand that FIG. 3 schematically illustrates nozzles 65' and 65'' simultaneously adding two different reagents R1 and R2. One would further understand, based on the written description noted above, and without necessitating further drawing figures, that the delivery may be sequential, for example, nozzle 65' first dispenses reagent R1, once reagent R1 has been dispensed, nozzle 65'' dispenses reagent R2. Thus sequential operation can be readily understood based on FIG. 3. Specifically, absence of R2 in FIG. 3 corresponds to a first step of dispensing R1 and absence of R1 corresponds to a second step of dispensing R2. Thus described, operation can be understood without unnecessary redundancy of figures.

Applicants respectfully traverse the Examiner's rejection of claim 54. The Examiner is correct in noting that the axis of rotation does not extend through each reaction vessel but extends through the center of the rotor. In fact, rotor 47 spins about axis of rotation 51. *See* FIG. 2; claim 32. Microtiter plate 42 is mounted on rotor 47 to spin about axis of rotation 51. *See* FIG. 2; claim 53. Wells 41, which are located in microtiter plate 42, similarly spin about the axis of rotation 51. *See* FIG. 2; claim 53. Thus, the spacial relationship of wells 42 and the axis of rotation 51 is defined. The application, as originally filed, describes that the rotor may be configured such that the orientation of the wells can vary with respect to the axis of rotation. For example, microtiter plate 42 may tilt during centrifugation. *See* FIG. 8b; page 18, lines 37 *et seq.* In the event that a substantially-vertical egress aperture (e.g., aperture 129) is provided on the bottom of a well of a tilting microtiter plate, such an aperture will extend to some degree radially

AMENDMENT AND REPLY

15 of 23

(1149756)

**BEST AVAILABLE COPY**

PATENT

Attorney Docket No. A-68717-2/RMS/VEJ  
Application No. 09/881,052

outward with respect to the axis of rotation. Furthermore, FIGS. 12a, 12b, and 13 disclose wells having egress apertures which extend parallel to the centrifugal forces exerted on the wells (e.g., arrow CF in FIG. 11b; arrow EL in FIG. 12b). One would appreciate that centrifugal forces generated by spinning the wells about axis of rotation 51 extend radially outward from the axis of rotation. Furthermore, the embodiment of FIGS. 10a to 10c disclose wells formed of a porous polymeric material. *See* page 20, lines 13 *et seq.* The porosity of the material does not support liquid under the higher forces of centrifugation. *See* page 20, lines 36-39. Thus, the pores of the material provide at least an egress aperture, if not many egress apertures, which extends in at least a one direction radially outward from the axis of rotation. Claim 54, as presently pending, is generic to the above mentioned embodiments, whereas claim 55 is specific to the porous material embodiment.

The Examiner has rejected claim 51 under 35 U.S.C. §112, second paragraph as failing to particularly point out and distinctly claim the invention. Applicants respectfully submit that the rejection of claim 51 is overcome by the accompanying amendment thereto.

***Rejections under 35 U.S.C. § 102 and 103******Claims 32-58 and 59-76***

The Examiner has rejected claims 32-58 and 59-76 under 35 U.S.C. § 102 and 103 as being anticipated by, or unpatentable over one or more of the following references: U.S. Patent No. 4,042,338 to Huber ("the Huber patent") and UK Specification No. 1,241,539 to American Hospital Supply Corporation ("the American specification"), U.S. Patent No. 6,423,536 to Jovanovich et al. ("the Jovanovich patent"), International Publication No. WO 99/25470 to Lebl ("the Lebl publication"), Japanese Publication No. 59-119268 to Sasao ("the Sasao publication"), the technical report by Lebl entitled "A New Approach to Automated Solid Phase Synthesis Based on Centrifugation of Tilted Plates" ("the Lebl report"), the webpage entitled "Spyder Technology: A New Approach to Automated Solid Phase Synthesis Based on Centrifugation of Tilted Plates" ("the Spyder webpage"), U.S. Patent No. 4,808,380 to Minekane ("the Minekane patent"), U.S. Patent No. 4,837,159 to Yamada ("the Yamada patent"), and U.S. Patent No. 5,472,672 to Brennan ("the Brennan patent").

AMENDMENT AND REPLY

16 of 23

(1149756)

## BEST AVAILABLE COPY

PATENT

Attorney Docket No. A-68717-2/RMS/VEJ  
Application No. 09/881,052

The Huber patent, the American specification, the Jovanovich patent, the Lebl publication, the Sasao publication, the Lebl report, the Spyder webpage, the Minekane patent, the Yamada patent, and the Brennan patent, taken individually or combined, fail to teach or suggest the apparatus of the present invention including a rotor carrying an array of reaction vessels along a circular path about an axis of rotation in combination with a controller for moving a liquid dispenser head, which has a plurality of *valved* dispensing nozzles, *about the axis of rotation along the circular path*, and for selectively dispensing liquid into two or more respective reaction vessels simultaneously, as is called for by independent claims 32 and 59, as presently amended.

In accordance with the present invention, reagent dispenser head 60 is mounted on a translation frame 62 which is configured to move dispenser head 60 with respect to the support surface 49. *See* page 11, lines 28 *et seq.* Dispenser head 60 is configured for moving along the circular path of microtiter plate 42, that is, along the fixed arcuate path of microtiter plate 42 as it spins with rotor assembly 46. *See* page 12, lines 1-5. Dispenser head 60 includes an array of valved dispensing nozzles 65 which may simultaneously address corresponding wells of microtiter plate 42. *See* page 12, lines 33-34. Since dispenser head 60 is configured to move along the circular path of microtiter plate 42, the array of valved dispensing nozzles 65 are similarly configured to move along the circular path.

The Huber patent does not disclose such features. Instead, in one embodiment the Huber patent discloses an automatic sample preparation device having a delivery pump assembly 24, which includes a support frame 26 for reciprocal horizontal movement on support bars 28, as indicated by arrow 30. *See* column 3, lines 47-54; FIG. 1. In another embodiment, delivery pump assembly 24 includes a support member 50 for vertical movement. *See* column 5, lines 28-46; FIG. 2. In still another embodiment, delivery assembly 24 rotates sampling probes 62 about an axis of the support member 64 so that in one position they dip into a sample contained in a sample storage vessel 68, and in another position they dip into the sample containers 12. In yet another embodiment, delivery assembly 24 includes a drive device 52 for vertically moving the sampling probes 48. *See* column 6, lines 57-60; FIG. 4.

AMENDMENT AND REPLY

17 of 23

(1149756)

PATENT

Attorney Docket No. A-68717-2/RMS/VEJ  
Application No. 09/881,052

The Huber patent fails to teach or suggest moving a liquid dispenser head about the axis of rotation along the circular path, much less a liquid dispenser head having valved nozzles moving along the circular path as is called for by claim 32. Instead, the Huber patent teaches away from the present invention in that Huber's dispensing probes 48 move substantially perpendicular to the circular path. In particular, the pump assembly of FIG. 1 moves substantially radially with respect to drive shaft 14. The pump assemblies of FIGS. 2 and 4 move substantially parallel with respect to drive shaft 14. And the pump assembly of FIG. 3 pivots dispensing probes 48 about an axis (i.e., the longitudinal axis of support member 64) that is substantially perpendicular to drive shaft 14. None of the embodiments teach or suggest moving about the axis of rotation along the circular path.

Nor does the American specification disclose such features. Instead, the American specification discloses a cell-washing centrifuge having a tube 15 which delivers liquid from a reagent supply 13, via reagent flow control 16, into an annular manifold chamber 46. Although the annular manifold chamber 46 and its nozzles 48 moves with head 13 and drive shaft 19, the chamber/nozzle assembly is not a dispenser<sup>1</sup>, it is a manifold<sup>2</sup>. In fact, the American specification teaches away from the present invention in that manifold chamber 46 is a passive conduit or passageway that does not include valves and is thus incapable of selectively metering out liquid, much less metering out different liquids into different sets of test tubes. Instead, a valve (i.e., reagent flow control 16) is provided to control liquid flow, which flow control is located in casing 11 outside of well 18 and thus cannot rotate with either head 13 or drive shaft 19. See FIG. 3. Thus, the American specification fails to teach or suggest a liquid dispenser head having valved nozzles which moves along a circular path.

With respect to the Examiner's characterization of American's manifold chamber 46 as a "multi-channel" dispenser, Applicants note that manifold chamber 46 is indiscriminate in its

<sup>1</sup> Dispense: to deal out in portions. See MERRIAM-WEBSTER ONLINE ([www.Merriam-Webster.com](http://www.Merriam-Webster.com)), 2004, Merriam-Webster, Incorporated. Springfield, MA (printout attached).

<sup>2</sup> Manifold: a pipe fitting with several lateral outlets for connecting one pipe with others; a fitting on an internal combustion engine that directs a fuel and air mixture to or receives the exhaust gases from several cylinders. See MERRIAM-WEBSTER ONLINE ([www.Merriam-Webster.com](http://www.Merriam-Webster.com)), 2004, Merriam-Webster, Incorporated. Springfield, MA (printout attached).

PATENT

Attorney Docket No. A-68717-2/RMS/VEJ  
Application No. 09/881,052

delivery of liquid from tube 15 to test tubes 26. The manifold chamber is simply incapable of delivering directing a first reagent to a first set of test tubes and a second reagent to a second set of test tubes. Any reagent delivered to manifold chamber 46 will be delivered to all test tubes 26, most likely in substantially equal portions to each of the test tubes. Thus, manifold chamber 46 is a single-channel device, which is consistent with American's use of the term "manifold".

With respect to the Examiner's position that the American specification discloses a controller "actuates" nozzles 48 of manifold chamber 46, Applicants note that nozzles 48 are merely passageways directing liquid flow from the manifold chamber 46 into test tubes 26. The nozzles have no valves or moving parts and thus have nothing to actuate. Instead, timing and synchronizing means 36 actuates "a suitable valve 16" that delivers liquid through tube 15 into manifold chamber 46 and, in turn, through nozzles 48 into test tubes 26. See page 2, lines 29-37; FIG. 3. It is valve 16 that is actuated, not the nozzles.

Similarly, the Jovanovich patent teaches away from the present invention. The Jovanovich patent discloses a biochemical reaction system utilizing a capillary cassette 15 to deliver liquid from a dispensing device location 122 to a multiwell plate 36. See e.g., FIGS. 1 and 5B; column 10, lines 24 *et seq.* Jovanovich's dispensing device does not move along the circular path of a rotor. See *id.* Instead, capillary cassette 15 moves with multiwell plate 36 along a circular path of rotor 41. See FIGS. 5A and 5B; column 10, lines 53 *et seq.* Like American's manifold, capillary cassette 15 is a passive conduit or passageway that is incapable of metering out fluid. In particular, capillary cassette 15 temporarily holds liquid, which has already been dispensed at the dispensing device location 122. See *id.* Capillary cassette 15 is not a dispenser but is instead a passive component of the Jovanovich's system that is at the mercy of externally imposed centrifugal force (see FIG. 5A; column 10, lines 53 *et seq.*) or externally imposed air displacement (see FIGS. 4A-C; column 11, lines 42 *et seq.*). Moreover, Jovanovich's capillary cassette 15 delivers all fluid at the same time, indiscriminately. In particular, once centrifugal force or air pressure is sufficient, all of the capillary tubes of capillary cassette 15 will empty, likely at substantially the same time. Thus, capillary cassette is incapable of selectively dispensing liquid in the manner of the present invention.

AMENDMENT AND REPLY

19 of 23

(1149756)

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PATENT

Attorney Docket No. A-68717-2/RMS/VEJ  
Application No. 09/881,052

Moreover, Jovanovich's capillary cassette 15 lacks valved nozzles. Tube segment 12 is merely a segment of tubing. Even if one were to consider capillary tube segment 12 as a nozzle, tube segment 12 lacks a valve or any moving parts. Since tube segment 12 has no valve or moving parts, tube segment 12 has nothing to actuate.

Thus, the Jovanovich patent fails to teach or suggest a liquid dispenser head having valved dispensing nozzles and movable along along the circular path of a rotor. In fact, the Jovanovich patent teaches away from the present invention in that the valved dispensing device is located at a location remote from the rotor, namely, at dispensing device location 122.

The Lebl publication also fails to teach or suggest a liquid dispenser head that which moves along the circular path of a rotor. In particular, the Lebl publication discloses mounting a liquid distributor above a centrifuge rotor but does not teach or suggest movement of the liquid distributor. Instead, the Lebl publication teaches away from the present invention in that the Lebl publication teaches moving the rotor and plate. For example, Lebl's liquid distributor "can deliver solvent or solutions of reagents from six different bottles into the plate *positioned under the needles of the distributor.*" See page 8, lines 30-33 (*emphasis added*). In order to position the plate under the distributor, the rotor is coupled to a stepper motor for precisely positioning a microtiter plate under the delivery head. See page 17, lines 22-29.

In the rejection of various claims dependent from claim 32, the Examiner further relied on additional references, including the Sasao publication, the Lebl report, the Spyder webpage, the Minekane patent, the Yamada patent, and the Brennan patent, in combination with one or more of the primary references discussed above. Applicants respectfully submit that the additional references fail to account for the deficiencies of the Huber patent, American specification, Jovanovich patent and Lebl publication.

For example, while the Sasao publication discloses a slider 11 that is movable in an (x) direction and a (y) direction, the Sasao publication does not appear to teach or suggest slide 11 to move along an arcuate path (as opposed to linear stepwise motion), much less along the circular path of reaction chamber 2. Similarly the Lebl report and the Spyder webpage fails to suggest

AMENDMENT AND REPLY

20 of 23

(1149756)

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PATENT

Attorney Docket No. A-68717-2/RMS/VEJ  
Application No. 09/881,052

movement of a liquid dispenser head along the circular path of reaction vessels. Nor do the Minekane, Yamada and Brennan patents.

For at least these reasons, Applicants respectfully submit that the Huber patent, the American specification, the Jovanovic patent, the Lebl publication, the Sasao publication, the Lebl report, the Spyder webpage, the Minekane patent, the Yamada patent, and the Brennan patent, taken individually or combined, do not anticipate or render obvious independent claims 32 and 59. Applicant submits that claims 33-58 and 60-76, which depend from claims 32 and 59, respectively, are allowable over the cited art for at least the same reasons noted above.

#### ***Claims 77-84 and 85-88***

The Examiner has rejected claims 77-84 and 85-88 under 35 U.S.C. § 102 and 103 as being anticipated by, or unpatentable over various references, alone and in various combinations thereof. Claims 77-88 have been cancelled without prejudice or disclaimer. Applicants respectfully submit that the Examiner's rejections of claims 77-88 have been rendered moot by cancellation thereof.

#### ***Double Patenting***

The Examiner has rejected claims 32-88 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-18 of U.S. Patent No. 6,663,832 to Lebl *et al.* ("the Lebl patent"). Submitted herewith is a Terminal Disclaimer to Obviate a Double Patenting Rejection (37 CFR § 1.321(c)) and Certificate under 37 CFR § 3.73(b) ("Terminal Disclaimer") disclaiming the terminal part of any patent granted on the above-captioned application which would extend beyond the term of the Lebl patent. Applicants respectfully submit that the Examiner's nonstatutory double patenting rejection is overcome by the Terminal Disclaimer submitted herewith.

#### ***Other Matters***

Applicants respectfully submit that new claims 89-94 are allowable over the cited art of record. Similar to claims 32 and 59 discussed above, independent claims 89 and 92 require a

AMENDMENT AND REPLY

21 of 23

(1149756)

BEST AVAILABLE COPY



PATENT

Attorney Docket No. A-68717-2/RMS/VEJ  
Application No. 09/881,052

controller for moving (or controlling) the liquid dispenser head along a curved path and synchronizing the liquid dispenser head to simultaneously dispense liquid from two or more nozzles into two or more reaction vessels. The art of record, taken individually or combined, fails to disclose or suggest the such a controller for moving (or controlling) the liquid dispenser head in such a manner. For at least these reasons, Applicants submit that independent claims 89 and 92 and claims 90, 91, 93 and 94, dependant thereon, are allowable over the cited art of record.

### CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided below.

The Director is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extension of time or additional claims, and/or credit any overpayment to Deposit Account No. 50-2319 (Order No. 469249-00078; Docket No. A-68717-2/RMS/VEJ).

AMENDMENT AND REPLY

22 of 23

(1149756)

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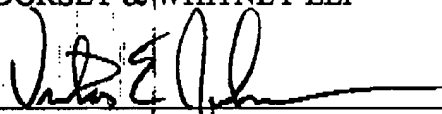
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Application No. 09/881,052

Prompt and favorable consideration of this Amendment and Response is respectfully requested.

Respectfully submitted,

DORSEY & WHITNEY LLP

Date: 8/23/2004

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Attachments: Printouts of "Dispense" and "Manifold" entries ([www.Merriam-Webster.com](http://www.Merriam-Webster.com))

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AMENDMENT AND REPLY

23 of 23

(1149756)



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One entry found for **dispense**:

Main Entry: **dispense** *dis-pen-sen(t)s*  
Pronunciation: *dis-pen(t)s*  
Function: *verb*  
Inflected Form(s) *dispensed; dispensing*  
Etymology: Middle English, from Medieval Latin & Latin; Medieval Latin *dispensare* to exempt, from Latin, to distribute, from *dis-* *dispensare* to weigh, frequentative of *pendere* to weigh; *dis-* *dis-* more at **SPIN**  
*transitive senses*  
1 *a* : to deal out *dispensed justice*  
*b* : **ADMINISTER** *<dispense justice>*  
2 : to give *dispensed him* : **EXEMPT**  
3 : to prepare and *dispense (medication)*  
*intransitive sense* *dispensed* : to grant *dispensation*  
synonym see **DISPENSE**  
- *dispense with* *dispensed with* : **DISCARD** *<dispensing with the usual introduction>*  
2 : to do without *<could dispense with such a large staff>*

For More Information on "dispense" go to [Britannica.com](http://Britannica.com)

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manifold[1,adjective]  
manifold[2,adverb]  
manifold[3,verb]  
manifold[4,noun]

Main Entry: **manifold**

Function: **noun**

: something that is manifold: as a : a whole that unites or consists of many of its elements <the manifold of aspirations, passions, frustrations -- Harry Slochower> b : a pipe fitting with several lateral outlets for connecting one pipe with others c : a fitting on an internal combustion engine that directs fuel and air mixture to or receives the exhaust gases from several cylinders c : **SET** 21 d : a topological space in which every point has a neighborhood that is homeomorphic to the interior of a sphere in Euclidean space of the same number of dimensions

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